DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 5, 2014

ReFlow Medical
Ms. Rebecca Pine
VP, Regulatory/Clinical Affairs & Quality Assurance
1003 Calle Sombra
San Clemente, CA 92673

Re: K141649
Trade/Device Name: speX Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 2, 2014
Received: October 2, 2014

Dear Ms. Pine,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141649

Device Name

speX Support Catheter, 50cm, 300006; speX Support Catheter, 90cm, 300007; speX Support Catheter, 135cm, 300008; speX Support Catheter, 150cm, 300009

Indications for Use *(Describe)*

The speX Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions or diagnostic/therapeutic agents

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Bram D. Zuckerman -S
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This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	ReFlow Medical
DATE PREPARED:	October 1, 2014
CONTACT PERSON:	Rebecca K Pine ReFlow Medical 1003 Calle Sombra San Clemente, CA 92673 Phone: (760) 809.5178
TRADE NAME:	speX Support Catheter
COMMON NAME:	Guide Catheter
CLASSIFICATION NAME:	Percutaneous Catheter
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 870.1250
PRODUCT CODE	DQY
PREDICATE DEVICES:	Volcano Valet Microcatheter (K112035) Quickcross Support Catheter (K072750) Minnie Support Catheter (K082337)

Substantially Equivalent To:
The speX Support Catheter is substantially equivalent in intended use, principal of operation and technological characteristics to the Volcano Valet Microcatheter (K112035), QuickCross Support Catheter (K072750), and the Minnie Support Catheter (K082337).

Description of the Device Subject to Premarket Notification:
The speX Support Catheter is a device intended to provide additional support to a steerable guidewire when accessing discrete regions of the peripheral vasculature. The device is an over the wire single lumen catheter with a proximal female hub and a distal flexible part with a radiopaque tapered tip. The distal end of the catheter has a lubricious coating. The speX Support Catheter is 0.035" guidewire compatible and has working lengths of: 50cm, 90c, 135cm and 150cm.

Indication for Use:
The speX Support Catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and

provide a conduit for the delivery of saline solutions or diagnostic/therapeutic agents.

Technological Characteristics:
The speX Support Catheter has similar physical and technical characteristics to the predicate device. All devices are highly flexible with a stabilizing radiopaque distal tip. In the case of the speX Support Catheter and the Volcano Catheter, both tips are shapeable. All devices utilize a luer hub handle. All devices are fabricated from medical-grade polymers with varying stiffness shafts. All devices are provided sterile and are intended for single-use. A summary of the similarities and differences between the speX Support Catheter and the identified predicates are shown in the table below:

	speX Support Catheter	**QuickCross Support Catheter (K072750)**	**Valet Mirocatheter (K112035)**	**Minnie Support Catheter (K082337)**
Function	Support catheter	Support catheter	Support catheter	Support catheter
Principle of Operation	Controlled penetration to create a channel across the occlusion	Controlled penetration to create a channel across the occlusion	Controlled penetration to create a channel across the occlusion	Controlled penetration to create a channel across the occlusion
Anatomical Site	Peripheral	Peripheral Coronary	Peripheral Coronary	Peripheral Coronary
Delivery to Site	Percutaneous access; over the wire	Percutaneous access; over the wire	Percutaneous access; over the wire	Percutaneous access; over the wire
Visualization	Radiographic imaging	Radiographic imaging	Radiographic imaging	Radiographic imaging
Flexibility	Highly flexible	Highly flexible	Highly flexible	Highly flexible
Working length	50cm 90cm 135cm 150cm	65cm-150cm	100cm-150cm	90cm-150cm
Crossing Mechanism	Distal Tip; Radiopaque; tapered	Distal Tip; Radiopaque marker Tapered	Distal Tip; Radiopaque tapered	Distal Tip; Radiopaque tapered
Crossing method	Forward (advancement) penetration of tapered tip	Forward (advancement) penetration of tapered tip	Forward (advancement) penetration of tapered tip	Forward (advancement) penetration of tapered tip
Use interface	Luer as handle	Luer as handle	Luer as handle	Luer as handle
Luer connector	Yes	Yes	Yes	Yes
Manually operated	Yes	Yes	Yes	Yes
Tip Material	Polymer	Polymer	Polymer	Polymer
Distal Tip OD	.022”	0.02” – 0.041”	0.02"	.0205"-0.0415"
Shapeable tip	Yes	No, available in straight or angled	Yes	No, available straight
Catheter Material	Polymer; varying stiffness shaft; braid reinforced; PTFE lining	Polymer; varying stiffness shaft; stainless steel braid (some models);	Polymer; varying stiffness shaft, metal braid	Polymer; metal braid incorporated into shaft
Hydrophilic coating	Yes, distal 40cm	Yes	Yes, distal 30cm	Yes, distal 40cm

	speX Support Catheter	QuickCross Support Catheter (K072750)	Valet Mirocatheter (K112035)	Minnie Support Catheter (K082337)
Catheter OD	4.6F	3.0-4.8F	1.8-3.5F	2.9-4.8F
Single use	Yes	Yes	Yes	Yes
Guidewire compatibility	0.035"	0.014" -0.035"	0.014" -0.035"	0.014" -0.035"
Targeted injection	Yes- saline solutions, diagnostic/therapeutic agents	Yes- saline solutions, diagnostic agents	Yes- saline solutions, contrast agents	Yes- saline solutions, diagnostic/therapeutic agents

Performance Data:
All necessary testing has been performed for the speX Support Catheter to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The device design was qualified through the following tests:

- Simulated Use (baseline, aged)
- Tensile Strength (baseline, aged)
- Torque (baseline, aged)
- Pressure Test (baseline, aged)
- Coating verification (baseline, aged)
- Corrosion Test (baseline, aged)
- Luer Verification (baseline, aged)
- Dimensional verification and visual inspections (baseline, aged)
- Sterilization Validation
- Biocompatibility
    - Cytotoxicity
    - Irritation
    - Sensitization
    - Materials Mediated Pyrogenicity
    - Acute Systemic Tox
    - Hemolysis (direct, indirect)
    - PTT
    - Complement Activation
    - Thrombosis

The speX Support Catheter met all specified criteria and did not raise new safety or performance questions.

Basis for Determination of Substantial Equivalence:
The data and information presented in this submission and the similarities and differences between the subject and predicate devices support a determination of substantial equivalence.. The speX Support Catheter is determined by ReFlow Medical, to be substantially equivalent to the identified predicate devices.